MINISTRY OF HEALTH
DEPARTMENT OF HEALTH FOR SCOTLAND

CENTRAL HEALTH SERVICES COUNCIL
SCOTTISH HEALTH SERVICES COUNCIL

Standing Joint Committee on Classification of Proprietary Preparations

REPORT ON

Classification in Category S

LONDON
HER MAJESTY'S STATIONERY OFFICE
1961

SIXPENCE NET

STANDING JOINT COMMITTEE ON CLASSIFICATION OF PROPRIETARY PREPARATIONS

Members

The Lord COHEN OF BIRKENHEAD, J.P., M.D., D.Sc., LL.D., F.R.C.P., F.F.R. (*Chairman*)

Professor STANLEY ALSTEAD, C.B.E., M.D., F.R.C.P., F.R.F.P.S.

A. B. DAVIES, ESQ., M.B., Ch.B., M.R.C.S., L.R.C.P.

Sir CHARLES DODDS, M.V.O., M.D., D.Sc., F.R.C.P., F.R.S.

Professor K. W. DONALD, D.S.C., M.A., M.D., D.Sc., F.R.C.P.

H. C. FAULKNER, Esq., M.R.C.S., L.R.C.P.

J. C. HANBURY, Esq., M.A., B.Pharm., F.P.S., F.R.I.C.

K. S. MAURICE-SMITH, Esq., M.R.C.S., L.R.C.P.

J. H. PEACOCK, Esq., Ch.M., F.R.C.S.

A. J. PITKEATHLY, Esq., O.B.E., M.B., Ch.B.

Professor J. K. RUSSELL, M.D., F.R.C.O.G.

D. E. SPARSHOTT, Esq., M.A., M.P.S.

Professor J. P. TODD, Ph.D., F.P.S., F.R.I.C.

Professor G. M. WILSON, M.D., F.R.C.P.

Professor L. J. WITTS, C.B.E., M.D., F.R.C.P.

ROY GOULDING, *Medical Joint Secretary*

W. G. HONNOR, *Joint Secretary*

Note

In their Report published in January 1959 the Standing Joint Committee on the Classification of Proprietary Preparations advised that proprietary preparations should be classified under five headings :—

Category N. New drugs of proved value which are not yet "standard" (the term "standard" was defined as meaning preparations described in the British Pharmacopoeia, the British Pharmaceutical Codex or the British National Formulary)

Category S. All preparations whose active therapeutic constituents are identical with, or modifications of, those of "standard" preparations; elegant preparations of drugs in category N; mixtures of drugs in category N with drugs in category S

Category P. Preparations which are not "standard" for which prima facie evidence of therapeutic value is presented but which the Committee cannot accept as of proved therapeutic value without further evidence, which must be supplied within a period stipulated by the Committee

and two others (categories O and H). They also gave advice on the prescribing of drugs in the several categories on form E.C.10.

Standing Joint Committee on Classification of Proprietary Preparations

REPORT ON CLASSIFICATION IN CATEGORY S

1. We have considered at the request of the Health Ministers whether it would help general practitioners in their prescribing if we subdivided the proprietary preparations now in Category S, and, if so, how this might most usefully be done.

2. Category S now contains:

(a) preparations whose active therapeutic constituents are identical with those of preparations described in the British Pharmacopoeia, British Pharmaceutical Codex and British National Formulary. (These may or may not have exact unbranded equivalents.)

(b) preparations whose active therapeutic constituents are modifications of those preparations described in the British Pharmacopoeia, British Pharmaceutical Codex and British National Formulary. (There are rarely any exact unbranded equivalents of these.)

(c) mixtures of drugs in Category N with drugs in (a) or (b) above.

(d) elegant preparations of drugs in Category N.

At present doctors have no ready means of knowing into which subdivision a Category S preparation falls. It will be seen that S is by no means synonymous with "standard".

3. We have decided that it would be useful to draw up a list of those preparations in the British Pharmacopoeia, British Pharmaceutical Codex or British National Formulary, available in unbranded form whose active therapeutic constituents are identical, quantitatively and qualitatively, with those of proprietary preparations falling under 2 (a) above, and we are doing this.

4. We have, however, decided not to attempt to categorise the remaining Category S preparations under other subheadings, but to adopt a different approach.

5. The preparations in Category S include under (a) in paragraph 2 some which differ only slightly from preparations in the British Pharmacopoeia, British Pharmaceutical Codex or British National Formulary in physical form, e.g., in vehicle or colour, but are otherwise equivalent (and these we consider should be listed along with the preparations referred to in paragraph 3 above); and under (b) in paragraph 2 some that have a slightly different chemical composition from drugs in the British Pharmacopoeia, British Pharmaceutical Codex or British National Formulary, but with similar therapeutic effects, e.g., sulphonamides, and the various antibiotics with slightly different spectra of action. We consider that general practitioners can best be assisted in distinguishing justifiable uses of these latter preparations by articles in the new *Prescribers' Journal*, by post-graduate courses and by other similar channels of information.

6. Amongst the preparations in Category S are many admixtures of which undiscriminating prescription could be questioned on therapeutic grounds for one or more of the following reasons:—

(a) they are combinations of drugs of similar action (e.g., of analgesics or hypnotics) which give no therapeutic advantage over standard single drugs in adequate dosage; or

(b) they include a fixed proportion of a drug to counter the untoward side effects of the main therapeutic agent, whereas good treatment demands that the quantity of the corrective should be determined by the need, which varies with each patient (examples are an opiate and aperient, or phenobarbitone and bemegride); or

(c) they combine in a fixed proportion drugs of differing and valuable therapeutic action, whereas the relative amounts should be determined by the individual patient's needs (an example is aspirin mixed with corticosteroids); or

(d) they include a preparation which is not regarded as therapeutically superior to standard preparations.

7. We have stated on previous occasions, and we remain of the same mind, that there should be no absolute restriction on the prescribing of any drug which in the general practitioner's view is necessary for the treatment of his patient. We consider, however, that the general practitioner need not normally go outside the drugs and preparations described in the British Pharmacopoeia, British Pharmaceutical Codex and British National Formulary together with drugs in categories N and P. Before he decides to prescribe any other preparation he should satisfy himself that the one chosen is better for his particular patient and that it is the only reasonable choice to make, as he may be called upon to justify his action if the cost of his prescribing is being formally investigated. The Health Departments should inform doctors from time to time of preparations in categories N and P.

8. Accordingly we restate our advice on the prescribing of category S as follows:

Preparations in Category S should be prescribable provided that

(i) they are properly prescribed as drugs (and not as foods, toilet preparations or household disinfectants);

(ii) they are not advertised direct to the public; and

(iii) the general practitioner who prescribes preparations which are not currently in the British Pharmacopoeia, British Pharmaceutical Codex or British National Formulary may be liable to be called upon to justify his action if the cost of his prescribing is being formally investigated.

COHEN OF BIRKENHEAD (*Chairman*)

ROY GOULDING (*Medical Joint Secretary*)

W. G. HONNOR (*Joint Secretary*)